K123623

510(k) Summary

FEB 1 4 2013

Submission Date: December 5, 2012

Submitter Information:

Alphatec Spine
5818 El Camino Real
Carlsbad, CA 92008

Ph# (760) 431-9286
Fax# (760) 431-0289

Contact:

Nadine Smith
Senior Regulatory Affairs Specialist
Ph# (760) 494-6717

Trade/Model Name: Illico MIS Posterior Fixation System

Common Name: Pedicle Screw System

Classification Regulation: 21 CFR 888.3070
Class III

Product Code(s): NKB, MNI, MNH

Device Description:

The Illico MIS Posterior Fixation System is a Noncervical Pedicle Screw and Rod System intended to facilitate the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The Illico MIS Posterior Fixation System provides implants and instruments for percutaneous and "mini-open" access and includes:

- Non-cannulated titanium polyaxial pedicle screws assemblies
- Cannulated titanium polyaxial pedicle screws assemblies
- Titanium set screws
- Titanium and Cobalt Chrome rods
- Instrumentation unique to the Illico MIS Systems

Indications for Use:

The Illico MIS Posterior Fixation System is intended for posterior, non-cervical, spinal fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. It is intended to provide stabilization during the development of fusion utilizing autograft or allograft bone graft. It is intended that this device, in any system configuration, be removed after development of solid fusion mass.

Substantial Equivalence Claimed:

The Illico MIS Posterior Fixation System is substantially equivalent to Alphatec Spine's previously cleared Icon/Zodiac Polyaxial Pedicle Screw System (K033090) and Zodiac Cannulated Polyaxial Spinal Fixation System (K042673, K071890, and K091189). The Illico MIS Posterior Fixation System instruments are substantially equivalent to instrumentation in Medtronic's CD Horizon System (K091442).

Technical Characteristics

The intended use and technological features of the Illico MIS Posterior Fixation System Implants do not substantially differ from the legally marketed predicate devices except that the predicate device is available with hooks and crossbars where the Illico MIS System does not. The Illico MIS Posterior Fixation System also includes instruments for minimally invasive access and implantation.

Non-Clinical Performance Testing

Construct testing was conducted in accordance with ASTM F-1717 including dynamic compression, static compression and static torsion. All testing met the acceptance criteria and the results were comparable to the predicate device.

Conclusion

The Illico MIS Posterior Fixation System was demonstrated to be substantial equivalent to the Illico MIS Implants is based on design, materials, intended use, and performance to the predicate systems identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Alphatec Spine, Incorporated
% Ms. Nadine Smith
Senior Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K123623
Trade/Device Name: Illico MIS Posterior Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: November 21, 2012
Received: November 23, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin F Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123623

Device Name: Illico MIS Posterior Fixation System

Indications For Use:

The Illico MIS Posterior Fixation System is intended for posterior, non-cervical, spinal fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. It is intended to provide stabilization during the development of fusion utilizing autograft or allograft bone graft. It is intended that this device, in any system configuration, be removed after development of solid fusion mass.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123623